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IN THE THIRD JUDICIAL DISTRICT COURT OF SALT LAKE COUNTY

WEST JORDAN DEPT., STATE OF UTAH

MARK SHURTLEFF, ATTORNEY GENERAL OF THE STATE OF UTAH ex rel. THE STATE OF UTAH, Plaintiff, vs. GLAXOSMITHKLINE, LLC, formerly SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, Defendant.	**ORIGINAL COMPLAINT AND JURY DEMAND** **Civil No.** 100423795 Roth

Plaintiff, the State of Utah (hereinafter "the State"), by and through its Attorney General, Mark Shurtleff, hereby complains of Defendant GlaxoSmithKline LLC, formerly SmithKline Beecham Corporation d/b/a GlaxoSmithKline (hereinafter "GSK"), and alleges as follows:

INTRODUCTION

1. This is a civil action for damages, restitution, civil penalties, and other monetary relief for violations of the Utah False Claims Act and other state common law and statutory causes of action stated herein brought by the Utah Attorney General in the exercise of his constitutional, common law, and statutory powers against GlaxoSmithKline LLC, formerly SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"). This action arises out of GSK's wrongful and illegal marketing, sale and promotion of the diabetes medication rosiglitazone maleate sold by GSK under the trade names Avandia®, Avandamet® and Avandaryl® (hereinafter referred to as "Avandia").

JURISDICTION AND VENUE

2. The Attorney General brings this action on behalf of the State of Utah pursuant to his authority under UCA § 67-5-1(18).

3. Jurisdiction over the subject matter of this Complaint is based, *inter alia*, upon UCA § 26-20-1, *et seq.*, which provides remedies to redress Defendant's actions under the Utah False Claims Act.

4. Personal jurisdiction over Defendant is proper under the Utah Long Arm Statute as codified in §§ 78B-3-201and 78B-3-205 of the UCA.

5. Venue is proper in the Third Judicial District and Salt Lake County pursuant to UCA § § 26-20-15 and 78B-3-307, in that many of the unlawful acts committed by Defendant were committed in Salt Lake County, including the making of false statements and misrepresentations

of material fact to the State of Utah, its departments, agencies, instrumentalities, and contractors, and to the Utah Medicaid Program.

6. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. §1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against Defendant. Nowhere herein does Plaintiff plead, expressly or implicitly, any cause of action or request any remedy which is founded upon federal law. The issues presented in the allegations of the instant Complaint do not implicate significant federal issues; do not turn on the substantial federal interpretation of federal law; nor do they raise a substantial federal question. Indeed, Plaintiff expressly avers that the only causes of action claimed, and the only remedies sought herein, are for those founded upon the statutory, common, and decisional laws of the State of Utah. Further, assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Accordingly, any improvident and dilatory attempt by Defendant to remove this case to federal court would be without a reasonable legal basis in fact or law.

PARTIES

7. Plaintiff, the State of Utah, is a body politic created by the Constitution and laws of the State of Utah, and as such, is not a citizen of any state. Mark L. Shurtleff is the duly-elected and present Attorney General of the State of Utah. The Attorney General brings this action in the exercise of his statutory and common law powers.

8. The Defendant GSK purports to be a limited liability corporation organized and existing under the laws of the State of Delaware but which has its principal place of business at One Franklin Plaza, 200 N. 16th Street, Philadelphia, Pennsylvania 19102.

9. At all times material hereto, Defendant GSK was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avandia.

10. At all times material hereto, Defendant GSK did business within the State of Utah by promoting, marketing, distributing and/or selling Avandia to the State of Utah, its departments, agencies, instrumentalities, and/or contractors, and to the general public.

11. Defendant GSK includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors and assigns and their present officers, directors, employees, agents, representatives, and other persons acting on their behalf.

12. Upon information and belief, in committing the acts alleged herein, each and every managing agent, agent, representative, and/or employee of the Defendant was working within the course and scope of said agency, representation and/or employment with the knowledge, consent, ratification, and authorization of GSK and its directors, officers, and/or managing agents.

13. Upon information and belief, Defendant GSK was formed as a result of the merger of pharmaceutical corporations Glaxo Wellcome, Inc. and SmithKline Beecham, Inc.

THE MEDICAID PROGRAM

14. The State of Utah's Medicaid program provides medical assistance to low income state residents. The primary purpose of the Medicaid program is to enable the State to furnish medical assistance on behalf of families of dependent children and of aged, blind or disabled individuals whose income and resources are insufficient to meet the costs of necessary medical services. The State of Utah enjoys a broad measure of flexibility in tailoring the scope and coverage of its

Medicaid plan.

15. The Medicaid program was created under Utah state law, pursuant to Title 26, Chapter 18 of the UCA. The Medicaid program is administered by the Division of Health Care Financing within the State's Department of Health. Pursuant to UCA § 26-18-2.3(1)(a), the Division shall establish, on a statewide basis, a program to safeguard against excessive payments.

16. Utah's Medicaid plan includes an optional prescription drug program. Pursuant to UCA § 26-18-2.4(1)(a), this plan provides care, including prescription drugs, that must be based upon clinical and cost-related factors, including "medical necessity." The Utah Administrative Code ("UAC") defines "medically necessary" in pertinent part as a drug that has no "equally effective course of treatment available or suitable . . . that is more conservative or substantially less costly." UAC R414-1-2(18)(b). R414-60-5 of the UAC provides, *inter alia,* that: "limitations may be placed upon drugs the same as imposed by manufacturers and the Food and Drug Administration (FDA);" "step therapy, requiring documentation of therapeutic failure with one drug before reimbursement for another drug in the same category may be used"; and "pharmacy reimbursement for some drugs is regulated by prior approval as described in the provider manual."

17. The State also has a State Medicaid Drug Utilization Review Board to recommend appropriate drug use for covered drugs, to review and approve Medicaid drug use criteria, including prior authorization criteria, and to otherwise advise the Division of Health Care Financing regarding drug utilization issues.

18. The State also has a Pharmacy and Therapeutics (P&T) Committee that provides recommendations for the Medicaid Preferred Drug List (PDL). The P&T Committee is charged with the responsibility to review drug classes to make recommendations to the Division of

Health Care Financing for PDL implementation. If clinical and therapeutic factors between drugs within the same class are substantially equal, then the P&T Committee shall recommend to the Division of Health Care Financing that it consider only cost.

19. The State relies on persons receiving payments and benefits from the Medicaid Program to "turn square corners" and to provide truthful and accurate information in their dealings with the Medicaid program and to abide by Utah law. However, the State's practical ability to monitor or police every one of the millions of claims submitted each year represents a loophole in the structure of the Medicaid program.

20. GSK has recognized and aggressively exploited this loophole in several ways. First, GSK has engaged in a direct, illegal, nationwide marketing program to promote the use of Avandia, asserting that Avandia was a "significant advance" in diabetes treatment. GSK affirmatively represented that Avandia was superior to existing drugs, such as metformin and sulfonylureas, at lowering diabetics' blood sugar, a critical goal in diabetes treatment. GSK did not just fail to disclose the potential cardiovascular risks Avandia posed, which include heart attacks and sudden cardiac death, it affirmatively represented that Avandia could reduce diabetics' cardiovascular risks. GSK has conducted this marketing effort knowing that prescriptions for Avandia are generally reimbursed by the Utah Medicaid Program.

21. Upon information and belief, GSK sought to increase the market for Avandia by manipulating Utah Medicaid procedures, and by directly and indirectly influencing employees of the State of Utah, its Drug Utilization Review Board, its P&T Committee Members and/or its advisory consultants, as well as prescribers and Medicaid recipients participating in the Utah Medicaid Program. As a result of GSK's efforts and exploitation of the Utah Medicaid program, the State has paid for inappropriate, unnecessary, and/or excessively-priced prescriptions for

Avandia which it must recover under Utah law. Moreover, under Utah law, the State must also recover the future costs of care for those Medicaid recipients rendered chronically ill or injured by Avandia's undisclosed side effects, as set forth herein.

FACTUAL BACKGROUND

22. Type 2 diabetes is the most common form of diabetes, afflicting 18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin (a hormone needed to convert sugar and other food into energy) or cannot effectively use the insulin it manages to produce.

23. Avandia, created and marketed by GSK, is purportedly designed to treat persons with Type 2 diabetes by helping sensitize cells to insulin, thereby assisting in blood-sugar control. It also is combined with metformin and sold as Advandamet®, and also was developed and sold as Avandaryl®. GSK began developing Avandia in the mid 1990's, and, in 1999, GSK received approval from the FDA to market Avandia in the United States. Avandia is a member of the class of drugs known as thiazolidinediones ("TZDs").

24. GSK's product Avandia can cause heart injury, excessive fluid retention, fluid- overload disease, liver damage, liver failure, stroke, and/or severe injury to the heart leading to cardiac arrest and death.

25. GSK knew or should have known about these adverse side effects since before it received FDA approval for Avandia in 1999, but failed to adequately warn the consumer public, prescribers, the FDA, and/or the State of Utah of these life threatening cardiovascular risks.

26. In preparation for seeking the FDA's approval to put the drug on the market, GSK conducted five clinical studies between 1996 and 1998 that revealed a high number of deaths among patients treated with Avandia. Eight Avandia patients suffered heart attacks or cardiac

deaths, as compared to only three in the control group. This data alone should have alerted GSK to Avandia's increased cardiovascular risk. Nevertheless, GSK failed to act on this data and continued its plan to seek FDA approval for Avandia.

27. On November 25, 1998, in spite of its knowledge of the drug's increased cardiovascular risks, GSK submitted Avandia's New Drug Application ("NDA") to the FDA.

28. Beginning in early 1999, while Avandia's New Drug Application was under consideration by the FDA, GSK's false and deceptive Avandia marketing campaign took form. GSK's targeted competitor drugs were not only other TZDs. Rather, GSK sought to achieve dominance in the Type 2 diabetes market by becoming the preeminent "first-line" drug of choice. It sought to replace not only other TZDs but also metformin and sulfonylureas—the established, ***much*** safer, and ***much*** cheaper diabetes drugs.

29. GSK manufactured Avandia and marketed it as a "wonder drug." From its launch in 1999 until independent medical studies made public Avandia's true medical risks, GSK successfully executed a massive, aggressive marketing campaign designed to obfuscate the risks of Avandia, asserting that Avandia was a "significant advance" in diabetes treatment. GSK affirmatively represented that Avandia was superior to existing drugs, such as metformin and sulfonylureas, at lowering diabetics' blood sugar, a critical goal in diabetes treatment. GSK did not just fail to disclose the potential cardiovascular risks Avandia posed, which include heart attacks and sudden cardiac death, it affirmatively represented that Avandia could reduce diabetics' cardiovascular risks. GSK knew or should have known that these representations were not true and likely to deceive. There simply was no scientific support for them. In fact, GSK knew or should have known even before the launch in 1999 that Avandia was no better at lowering blood sugar than existing medications, and that it posed serious increased

cardiovascular risks.

30. GSK spent hundreds of millions of dollars in a far-reaching, massive, and widespread promotional campaign to drive Avandia's sales. A highly sophisticated marketer of pharmaceutical products, GSK used its substantial sales, marketing, and public relations machines to create a false and misleading impression of the drug's safety and efficacy among consumers, prescribers, private insurers, public health care providers, public entities, and government payors, including the State of Utah.

31. Since 1999, GSK has spent millions of dollars on Direct to Consumer ("DTC") print and television advertising, aimed at convincing patients, including Utah Medicaid recipients, to request Avandia from their doctors. GSK's marketing campaign also targeted prescribers as well as the individuals, groups, and entities responsible for selecting the drugs covered by health coverage plans and/or included on pharmacy formularies. GSK sought to influence these targets through, among other tactics, print media, misleading promotional materials, lavish company-sponsored dinners, and "conferences." GSK produced and distributed "studies" whose sole purpose was to advance the company's marketing message and which were intended to, and did, deceive consumers, physicians, private insurers, public health care providers, public entities, and government payors, including the State of Utah.

32. GSK's Avandia message had two key components. First, GSK propagated the message that Avandia was better at lowering blood sugar than other established drugs. That is, Avandia had superior efficacy. GSK also represented that patients could stay on Avandia longer than the older drugs. Second, GSK represented that, unlike the established diabetes drugs, Avandia had the additional benefit of actually lowering diabetics' cardiovascular risks. The notion that Avandia would actually lower diabetics' cardiovascular risk was critical to Avandia's marketing.

GSK needed justification for the steep price difference between Avandia and the older established diabetes drugs. GSK, however, knew or should have known that these representations were false, misleading, and likely to deceive. At best, GSK had no data to support these claims. At worst, they were wholesale fabrications.

33. Indeed, upon information and belief, GSK has at all relevant times *known* that it lacked the scientific data to support its efficacy and safety claims. Instead, upon information and belief, GSK's marketing department planned to create scientific evidence to substantiate GSK's marketing claims by conducting company-sponsored "clinical trials" and "studies." On information and belief, company scientists lack the necessary independence in GSK's corporate structure to allow them to create scientific studies that meaningfully assess efficacy and safety; instead, they take direction from GSK's marketing department. On information and belief, GSK's marketing department routinely communicates with GSK scientists, directing them to design studies and trials to yield results that further the drug's product message. Thus, GSK scientists played a central role in GSK's marketing strategy by designing clinical trials and meta-analyses not to advance scientific inquiry into the drug's safety and efficacy, but to produce results consistent with (and hide results inconsistent with) GSK's preexisting advertising messages about Avandia.

34. Another central aspect of GSK's advertising campaign was restricting access to scientific data about Avandia that would support independent and critical assessments of the drug's safety. On information and belief, when GSK's scientists were unable to obtain the results for Avandia studies that the marketing department ordered, it was company policy to bury the unfavorable data either by not releasing it at all, or by obscuring the data's import by releasing only "summary findings" on the company's website, making the data impossible for independent

scientists to analyze effectively.

35. Another vehicle of GSK's tight message construction and control was its use of sales representatives who spread the Avandia message by calling on prescribers throughout the State of Utah. GSK even used seemingly independent physicians to disseminate its message. On information and belief, GSK paid doctors to act as speakers to deliver the company's messages about the drug at conferences and in other venues, and as writers who collaborated with GSK representatives in the "ghostwriting" of medical and scientific articles that sought to advance GSK's Avandia marketing agenda. "Ghostwriting" is a particularly insidious practice where a drug company authors a purportedly independent scientific paper and then pays someone else to place ***their*** name on the paper to give the appearance of independence and objectivity by suggesting that the independent person or group, and ***not*** the drug company, performed the research and authored the paper. This aspect of GSK's messaging campaign was particularly far-reaching and effective, as revealed by an independent study authored by doctors at the Mayo Clinic and published in the March 19, 2010 *British Medical Journal* ("BMJ"). The study surveyed 202 articles written about Avandia. The BMJ study found that out of the 31 unique authors who expressed "favourable opinions" of Avandia, 27 of them—an extraordinary 87 percent—had financial ties to GSK.

36. GSK's aggressive marketing campaign did not go unnoticed by the FDA. The FDA cited GSK for engaging in false and deceptive advertising for Avandia **before** the drug was even launched. The FDA cited GSK for precisely the core messages GSK contrived to promote, advertise, and market Avandia. In an April 23, 1999 press release, GSK improperly touted Avandia as "a significant advance in the treatment of diabetes and [as] highly effective in safely and significantly lowering blood sugar." GSK also improperly claimed that Avandia "can help

millions of people with Type 2 diabetes lower their blood sugar levels and help prevent life-threatening complications." As the FDA recognized, it is improper for a drug company to "represent in a promotional context that an investigational new drug is safe and effective" before receiving FDA approval.

37. On October 20, 2000, the FDA again found that GSK's promotional materials for Avandia, including print advertisements, were false and misleading. The FDA admonished GSK that "your presentations that Avandia decreases [glucose] by 2.3% are ***misleading*** because they suggest that Avandia is more effective than has been demonstrated by substantial evidence." (emphasis added). The FDA further found that other materials were "***misleading*** because they fail to present risk information with a prominence and readability reasonably comparable with the presentation of information related to the effectiveness of the drug." (emphasis added). In addition, more advertising material was found to "lack fair balance because materials present the product's indication without disclosing risks associated with Avandia."

38. On February 7, 2001, the FDA medical officer reviewing GSK's insulin NDA recommended rejecting the application based on mounting evidence of adverse cardiovascular events, such as heart attacks, linked to Avandia. That same FDA medical officer concluded that the safety information was "quite troublesome." In addition to mounting safety concerns, GSK continued to receive adverse event reports and other information that confirmed that its claims of Avandia's superior efficacy and greater safety over established diabetes drugs were false. Despite all this, GSK continued its false and deceptive campaign at full speed.

39. On June 28, 2001, the FDA cited GSK for a ***third*** time during its coordinated Avandia marketing campaign, this time for "direct-to-consumer (DTC) broadcast and print advertisements for Avandia that are ***false and misleading.***" (emphasis added). The FDA found these

advertisements to be false and misleading because they presented incomplete and deceptive information about the use of Avandia with insulin. Furthermore, the advertisements minimized the required warning information because they failed to use "consumer-friendly language and therefore [were] unlikely to be understood by consumers." The FDA further noted that GSK continually made statements in its advertising that undercut and minimized the FDA-required bolded warnings relating to Avandia.

40. On July 17, 2001, the FDA issued a Warning Letter to Defendant arising from oral misrepresentations made by Defendant at the 10th Annual American Association of Clinical Endocrinologists (AACE) Meeting in San Antonio, Texas, on May 2-6, 2001, which denied the existence of serious new risks associated with Avandia at GSK's promotional exhibit booth. Additionally, GSK displayed exhibit panels (AV013G) at this meeting that minimized new risks associated with Avandia. The FDA found that Defendant's "promotional activities that minimize serious new risks are particularly troublesome because we have previously objected, in two untitled letters, to your dissemination of promotional materials for Avandia that failed to present any risk information about Avandia or minimized the hepatic risk associated with Avandia. Despite your assurances, such violative promotion of Avandia has continued."

41. The individual violations for which the FDA cited GSK in 2000 and 2001 were not isolated incidents. Instead, they were integral components of GSK's entire coordinated marketing campaign—a campaign that was, as a whole, driven by the aim of misleading the public, the medical community and payors, including the State of Utah, about Avandia's efficacy and safety. While the FDA focused on these individual violations, GSK got away with countless other deceptions that contributed to its overarching goal of suppressing adverse information and disseminating false or misleading positive information about Avandia.

42. On March 25, 2008, the FDA sent another Warning Letter to GSK wherein the FDA outlined its findings following an inspection at GSK's corporate headquarters located in North Carolina. The inspection focused on GSK's "compliance with Postmarketing Adverse Drug Experience (PADE) reporting requirements and other postmarketing reporting requirements related to Avandia (rosiglitazone maleate) approved by the FDA on May 25, 1999, under NDA 21-071." The FDA inspection revealed that GSK:

> failed to report data relating to clinical experience, along with other data and information, for Avandia, as required under Section 505(k)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 US.C. §355(k)(1)] and Title 21 of the Code of Federal Regulations (21 CFR) Section 314.80 and 314.81. In particular, the inspection found that your firm failed to report multiple postmarking studies involving Avandia in mandatory Periodic and/or NDA Annual Reports. Failure to comply with Section 505(k) of the Act is a prohibited act under Section 301(e) of the Act [21 U.S.C. § 331(e)].

43. The FDA stated in its Warning Letter that "the specific violations noted in this letter are *serious* and may be *symptomatic* of underlying postmarketing safety reporting failures." (emphasis added). The letter was not an inclusive list of all violations and the FDA reminded GSK that "[i]t is your responsibility to ensure adherence to each requirement of the Act and its regulations." (emphasis added).

44. In addition, GSK threatened and intimidated physicians who were raising concerns regarding the cardiac risk of Avandia.

45. In 1999, John B. Buse, M.D., a diabetes expert and head of endocrinology at the University of North Carolina at Chapel Hill, was involved as an investigator in a rosiglitazone study. Following his investigational efforts, he gave a number of speeches at scientific meetings where he opined that rosiglitazone may carry cardiovascular risks.

46. GSK attempted to silence Dr. Buse by threatening him with a $4 million lawsuit,

characterizing him as a liar and telling Dr. Buse's department chair that he was "for sale." In response to GSK's pressure, Dr. Buse sent a three-page letter to the then Chairman of Research and Development, Dr. Tadktaka Yamada. Dr. Buse wrote, "I may disagree with GSK's interpretation of that data...I am not for sale ... Please call off the dogs. I cannot remain civilized much longer under this kind of heat." Eventually, after the intimidation, Dr. Buse signed a statement that GSK used to help ease investor concerns.

47. Nevertheless, on March 15, 2000, Dr. Buse wrote a letter to the FDA again raising concerns about a "worrisome trend in cardiovascular deaths and severe adverse events" associated with Avandia:

> I would like you to know exactly what my concerns are regarding rosiglitazone as a clinical scientist and my approach as a clinician. On the basis of the increase in LDL concentration seen in the clinical trial program (whether the number we accept as the truth is the 18.6% at 4 mg bid in the package insert or the "average of 12%" now being discussed) one would expect an increase in cardiovascular events.... Based on studies with statins and plasmapheresis, changes in LDL concentration can be associated with substantial changes in vascular reactivity and endothelial function over a time course of days to weeks.
>
> In short, the lipid changes with troglitazone and pioglitazone can only be viewed as positive. They are very similar in nature.... As mentioned above, I remain concerned about the lipid changes with rosiglitazone....Rosiglitazone is clearly a very different actor. I do not believe that rosiglitazone will be proven safer than troglitazone in clinical use under current labeling of the two products. In fact, rosiglitazone may be associated with less beneficial cardiac effects or even adverse cardiac outcomes.

48. After hearing allegations that Dr. Buse was intimidated, the United States Senate Committee on Finance ("Senate Finance Committee") began an investigation and "intensive review" of documents and found that "it is apparent that the original allegations regarding Dr.

Buse and GSK's attempts at silencing him are true; according to relevant emails, GSK executives labeled Dr. Buse as a "renegade" and silenced his concerns about Avandia by complaining to his superiors and threatening a lawsuit."

49. The Senate Finance Committee stated in its report that "[t]he documents in the Committee's possession raise serious concerns about the culture of leadership at GSK. Even more serious perhaps is our fear that the situation with Dr. Buse is part of a more troubling pattern of behavior by pharmaceutical executives."

50. The Senate Finance Committee noted that "[t]he effect of silencing this criticism is, in our opinion, *extremely serious.* At a July 30, 2007, safety panel on Avandia, FDA scientists presented an analysis estimating that Avandia caused approximately 83,000 excess heart attacks since coming on the market. Had GSK considered Avandia's increased cardiovascular risk more seriously when the issue was first raised in 1999 by Dr. Buse, instead of trying to smother an independent medical opinion, some of these heart attacks may have been avoided."

51. GSK's marketing strategy was wildly successful. Through 2007, GSK's U.S. Avandia sales topped $7 billion. But as Avandia revenue streamed into GSK, additional information began to come to light that belied GSK's claims of Avandia's superiority over the older and cheaper diabetes drugs and of its purported ability to reduce diabetics' cardiovascular risks. Indeed, GSK, through its own internal studies and reports from the field (called serious adverse event reports, or "SAEs"), collected reams of data showing that Avandia dramatically ***increased*** diabetics' cardiovascular risks. But rather than informing the public about these dangers, GSK suppressed the data and studies for fear they would undermine the drug's core marketing messages.

52. As serious cardiac adverse event reports continued to pour in, GSK decided that, in addition to its policy of concealing the data on Avandia's increased cardiovascular risks, it needed to prepare for offensive action to convince diabetics, the U.S. medical community, and payors, including the State of Utah, that Avandia was safe. Thus, in 2004 it began marshalling, filtering, and selectively disseminating the data and studies it had been collecting regarding Avandia's cardiac risks.

53. In 2005, GSK concluded its own meta-analysis of data concerning Avandia's effect on diabetics' risk of heart attacks. Stunningly, GSK's own meta-analysis found that Avandia increased diabetics' risk of heart attacks by at least ***an additional 31%***. Yet, when GSK informed the FDA about its meta-analysis in September 2005, it minimized the significance of its own conclusions by stating merely that they "may" signal an increased risk for heart attacks in diabetics. GSK did not inform the State of Utah of GSK's now undeniable knowledge of the increased cardiovascular risk associated with the use of Avandia. Instead, its false and deceptive marketing campaign continued full speed ahead.

54. In August of 2006, GSK finally sent to the FDA and the European Medicines Agency ("EMEA") the results of its 2005 meta-analysis showing that use of Avandia caused a 31% increase in diabetics' already elevated heart attack risk. Within two months, the EMEA ordered GSK to put the results of its meta-analysis on its warning label. Meanwhile, in the United States, GSK continued to minimize Avandia's risks.

55. While intentionally failing to warn of Avandia's known increased cardiovascular risks, GSK continued to tout "studies" consistent with its marketing message. On September 23, 2006, GSK published the results of its DREAM (Diabetes Reduction Assessment with Rampiril and Rosiglitazone Medication) study. The DREAM study allegedly investigated whether Avandia

could prevent diabetes by examining the effect of Avandia on non-diabetics. While treatment with Avandia was associated with a lower risk of diabetes for pre-diabetic subjects as compared to a placebo, subjects taking Avandia had a higher incidence of heart attacks than the control group. Some scientists sharply criticized the DREAM study, noting that GSK appeared to be focused largely on marketing questions by focusing on a pre-disease state and not concentrating on addressing the pressing questions surrounding Avandia's increased risk of heart attacks for the population to whom the drug was actually marketed.

56. In December 2006, GSK released the results of its ADOPT (A Diabetes Outcome Progression Trial) study in the New England Journal of Medicine (*"NEJM"*). As an integral part of GSK's marketing campaign, the ADOPT study compared Avandia to metformin and another drug called glipizide (also known as glyburide) to "compare" their glycemic control efficacy. GSK had promised the FDA that ADOPT would study, among other things, the long-term safety of Avandia, including cardiovascular risks. However, cardiovascular events were neither identified nor recorded in a systematic fashion in the ADOPT study. Heart failure was the only outcome it reviewed and measured. GSK ignored data about other cardiovascular events, such as non-fatal heart attacks—data that would have been valuable in assessing Avandia's cardiovascular risks. GSK knew there were many serious cardiovascular issues associated with Avandia aside from heart failure, but it failed to investigate these risks even when it had the opportunity to do so. Nonetheless, as two prominent researchers observed in an editorial in the *NEJM,* "even though misclassification and incomplete ascertainment of events effectively reduce the ability of a study to detect a difference in event rates, [Avandia] in ADOPT was associated with a higher risk of cardiovascular events, including heart failure, than glyburide."

57. On May 21, 2007, Dr. Steven E. Nissen, a prominent cardiologist associated with the

Cleveland Clinic, published a study in the NEJM of his analysis of 42 studies comprising of approximately 28,000 people who took Avandia. These were on-line databases of GSK studies that were available on the Internet. Dr. Nissen's meta-analysis revealed a 43% higher risk of heart attack for those taking Avandia compared to people taking other diabetes drugs or no diabetes medication, and people taking Avandia suffered such adverse effects at a rate of 1.99%, as opposed to 1.51% for other patients. Further, Dr. Nissen's analysis showed a 64% elevated risk of death from cardiovascular causes.

58. In the same *NEJM* issue, two other prominent scientists stated in an editorial that, "[i]insofar as the findings of Nissen...represent a valid estimate of the risk of cardiovascular events, rosiglitazone represents a major failure of the drug-use and drug-approval process in the United States." GSK had all this data available at its fingertips for years, but it had at a minimum ignored the data, or at worst covered it up. Although GSK scientists had the ability and duty to analyze this data, GSK failed to take any action, all the while aggressively marketing Avandia. Indeed, internal GSK e-mails show that GSK's own scientists ***confirmed*** the accuracy and validity of the Nissen analysis.

59. In a December 2007 floor speech, Senator Grassley, the Chairman of the Senate Finance Committee, revealed that Dr. Steve Haffner, a professor of medicine at the University of Texas Health Sciences Center, San Antonio, and a consultant for GSK, had leaked to GSK a draft of the Nissen article before it was published by the*NEJM.* Dr. Haffner was entrusted with a confidential copy of the manuscript draft because he was peer-reviewing the study for the *NEJM.*

60. According to documents produced by GSK to the Senate Finance Committee, the leaked manuscript was widely disseminated within the Company, allowing GSK to launch a public relations plan in an effort to protect Avandia. The Senate Finance Committee staff reviewed

documents showing that over forty executives at GSK received and/or learned of the results in the leaked study, including then CEO Dr. Jean-Pierre Garnier; head of research, Dr. Moncef Slaoui; Vice President of Corporate Media Relations, Nancy Pekarek; and GSK Senior Advisor, Sir Collin Dollery.

61. Before Dr. Nissen's study on Avandia was published, GSK's statistical experts were examining the study for potential flaws. In addition, GSK officials were drafting "key messages" to undermine the main conclusion of the Nissen study. One day after receiving the unpublished study from Dr. Haffner, GSK produced a detailed, 8-page analysis of Dr. Nissen's paper, weeks before the paper's public release. The GSK statistician attempted to find deficiencies in Nissen's meta-analysis but noted, "[t]he selection of trials therefore appears to be thorough, though others more familiar with the trials can comment more knowledgeably."

62. The GSK statistician also performed a regression analysis on each study that Dr. Nissen used in his meta-analysis to see if the effects of myocardial infarction and/or cardiovascular death would still appear. The statistician stated, "[t]hese results are very similar to the conclusion from the [Nissen] paper using the Peto method. As such there is no statistical reason for disregarding the findings as presented."

63. On May 9, 2007, Sir Colin Dollery, a senior consultant to GSK, laid out many of the problems with Avandia in an email to Dr. Slaoui and others. He wrote:

> To a great extent, the numbers are the numbers, the [Nissen] analysis is very similar to our own . . . We cannot undermine the numbers but I think they can be explained so we must concentrate on effective risk management.

64. After the publication of the Nissen study, GSK went on the offensive. On May 21, 2007, *NEJM* published online Dr. Nissen's meta-analysis that found a link between Avandia and heart attacks. That same day, GSK responded via press release and via a letter to healthcare providers

stating that, "GSK strongly disagrees with the conclusions reached in the *NEJM* article, which are based on incomplete evidence and a methodology that the author admits has significant limitations." Instead, GSK highlighted the results of company sponsored trials like RECORD (Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycaemia in Diabetes) as "the most scientifically rigorous way to examine the safety and benefits of a medicine." In a subsequent letter to *The Lancet*, GSK maintained that the RECORD trial is "compelling evidence" for the safety of Avandia, and that "the independent data safety monitoring board for RECORD recently reviewed an interim analysis of unblinded cardiovascular endpoints and confirmed that the trials should continue."

65. On June 5, 2007, GSK published the "interim results" of the RECORD study. The GSK study authors concluded that the data was "insufficient" to find a link between Avandia and heart attacks. It was no coincidence that GSK had these results prepared and ready for public dissemination so quickly after the publication of the Nissen article. Internal GSK emails indicate that GSK executives, not the study's independent steering committee, made the final decision to publish the RECORD trial results. Yet, in talking points created for its sales force, GSK stated, "because of the widespread media coverage of the *NEJM* [Nissen] meta-analysis and the confusion it has created, the RECORD Steering Committee decided it was important to publish the interim analysis in the interests of patient safety."

66. The Senate Finance Committee further noted that, based on a review of emails, the authors of the RECORD trial appeared more concerned about countering claims that Avandia may be associated with heart attacks, than in trying to understand the underlying science. While circulating a draft of a manuscript on the RECORD trial, one of the authors wrote to his

colleagues, "[W]hat's to stop [Nissen] adding the events from RECORD to his meta-analysis and re-enforcing his view?"

67. The RECORD study's stated purpose was to examine whether the "promising' impact of thiazolidinediones on insulin sensitivity and cardiovascular risk factors would translate into an improvement in cardiovascular clinical outcomes." The study also sought to "address concerns over cardiac failure[;] confirm that the better outcomes associated with improved glucose control, as reported by the UKPDS [the United Kingdom Prospective Diabetes Study], are applicable to this group of drugs; and allay concerns based on LDL [low-density lipoprotein] cholesterol concentrations rather than LDL particle atherogenicity." The publication of the RECORD study's interim results in June 2007 was the first that anyone in the United States, other than GSK, knew of the study's existence. GSK had failed to even report this study's existence to the FDA. GSK released these "interim results" (the study had not been completed), to give a "complete picture" of Avandia's cardiovascular risks. In fact, RECORD's results showed that GSK's claims about Avandia's superior efficacy and safety were both false. The RECORD study confirmed that Avandia offered no superior efficacy over established diabetes drugs. RECORD's "interim results" also showed that Avandia was associated with a 30% increased risk of heart failure. Minimizing and concealing the true results of its own RECORD study, GSK continued to claim that that the data was insufficient to support any conclusion about an increased risk of heart attacks.

68. The release of RECORD's "interim results" by GSK was calculated to prematurely publicize "conclusions" that were unsupported and, in fact, contradicted by the data from the study. Thus, for many scientists, RECORD raised more questions than it answered. As one researcher noted in an editorial in the *NEJM,* RECORD "seem[ed] to reflect a company-oriented

posture regarding rosiglitazone, rather than a neutral scientific inquiry." Further, the study had far too few participants, or "power," to extrapolate the study's findings beyond the study itself. In fact, GSK had been aware since at least 2004 that the RECORD trial was statistically inadequate or "underpowered" to answer questions regarding cardiovascular safety.

69. Despite GSK's best efforts, it could not stem the tide of data exposing Avandia's dangers. On July 30, 2007, the FDA released its own meta-analysis of 42 studies. Like the Nissen study, the FDA's analysis drew largely on raw data of which GSK had known for years. Like Nissen, the FDA's study found that Avandia significantly increased diabetics' risk of heart attacks and other serious cardiovascular events. The FDA's scientists found that Avandia use increased diabetics' already increased risk of serious cardiovascular events by ***an additional 42%***.

70. On the same day, the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA met jointly to examine the cardiovascular risks of Avandia. At that meeting, the FDA's Director for Science and Medicine in the Office of Surveillance and Epidemiology, Dr. David Graham, concluded that Avandia should be pulled from the market. His detailed presentation tracked a combination of results from long-term, placebo-controlled studies and meta-analyses to conclude that Avandia's benefits did not outweigh its cardiovascular risks. After the close of testimony, the two FDA committees officially concluded that Avandia posed greater cardiovascular risks than placebo.

71. The proceedings' chairman, Clifford M. Rosen, M.D., wrote in the August 9, 2007 edition of the *NEJM* that:

> The basic plot of the [Avandia] story quickly became obvious to the advisory committee: a new "wonder drug," approved prematurely and for the wrong reasons by a weakened and underfunded government agency subjected to pressure from industry, had caused undue harm to patients.

72. On August 14, 2007, the warnings, precautions and contraindications sections of the Avandia label were changed regarding the potential increased risk of heart failure, and the following new black box warning was added to the label:

> WARNING: CONGESTIVE HEART FAILURE
>
> Thiazolidinediones, including rosiglitazone, cause or exacerbate congestive heart failure in some patients (see WARNINGS). After initiation of AVANDIA, and after dose increases, observe patient carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed according to current standards of care. Furthermore, discontinuation or dose reduction of AVANDIA must be considered.
>
> AVANDIA is not recommended in patients with symptomatic heart failure. Initiation of AVANDIA in patients with established NYHA Class III or IV heart failure is contraindicated. (See CONTRAINDICATIONS and WARNINGS.)

73. On September 23, 2007, a third independent meta-analysis was published, this time by the Journal of the American Medical Association ("*JAMA*"). This analysis confirmed both the Nissen and the FDA's results, showing a 42% increase in heart attacks associated with Avandia use. The *JAMA* study concluded that Avandia "significantly increased the risk of myocardial infarction." Also in September 2007, a study published in the *Annals of Internal Medicine* concluded that, compared "with newer, more expensive agents [like Avandia], older agents (second-generation sulfonylureas and metformin) have similar or superior effects on glycemic control, lipids, and other intermediate endpoints."

74. On or about November 14, 2007, the warnings, precautions, and indications sections of the Avandia label were changed regarding the potential risk of myocardial ischemia, and the following language was added to the black box warning:

WARNING: CONGESTIVE HEART FAILURE AND
MYOCARDIAL ISCHEMIA

> A meta-analysis of 42 clinical studies (mean duration 6 months; 14,237 total patients), most of which compared AVANDIA to placebo, showed AVANDIA to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. Three other studies (mean duration 41 months; 14,067 patients), comparing AVANDIA to some other approved antidiabetic agents or placebo, have not confirmed or excluded this risk. In their entirety, the available data on the risk of myocardial ischemia are inconclusive.

75. Despite the evidence establishing otherwise, GSK continued to deny evidence of the increased cardiovascular risks associated with Avandia. In December 2007, in response to the *JAMA* meta-analysis, GSK baldly stated in a press release that "there is no consistent or systematic evidence that [Avandia] increases the risk of myocardial ischemic events or deaths in comparison to other anti-diabetic agents."

76. In February 2010, following a two-year investigation that involved the review of over 250,000 pages of documents provided by GSK, the FDA, and others, the Senate Finance Committee published its "Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia." Among other things, the report concluded:

> The totality of the evidence suggests that GSK was aware of the possible cardiac risks associated with Avandia years before such evidence became public. Based on this knowledge, GSK had a duty to sufficiently warn patients and the FDA of its concerns in a timely manner. Instead, GSK executives intimidated independent physicians [and] focused on strategies to minimize findings that Avandia may increase cardiovascular risk . . .

77. The Senate Finance Committee's investigation revealed that, as far back as 2000, internal emails show that GSK executives sought to downplay scientific findings, which raised questions about the safety of Avandia. For example, in an internal email sent on October 23, 2000, a GSK

executive sought to downplay the fact that Avandia gave a worse lipid profile than Actos. At the time, GSK executives were concerned about a GSK study of Actos, called Study 175. In that email, a GSK executive wrote, "This was done for the US business, way under the radar and we lost in terms of LDL and Tgs . . . Per Sr. Mgmt request, **these data should not see the light of day** to anyone outside of GSK." (emphasis supplied).

78. In another email sent on July 6, 2001, GSK executives discussed not wanting to do a head to head trial between Avandia and Actos because of Study 175. In that email, a GSK executive wrote, "I agree that there is no benefit in doing a head to head study with [ACTOS] as the best result would be equivalence.

79. The Senate Finance Committee expressed concern that Study 175 was not turned over to the FDA in a timely manner. A deputy director at the FDA Office of Drug Safety was asked whether it would "have been important . . . to know that in 2001 GlaxoSmithKline found that they lost against its competitor Actos" and responded:

> . . . any information pertaining to a serious adverse event, such as myocardial infarction, and especially death, is a high alert for any safety officer at the FDA. So any information, including something like this, because the lipid profile go to some biological mechanism by which maybe one drug may have more safety – adverse event than another within the same drug class, it would be extreme [sic] important information for someone in my position to consider.

80. On a separate occasion, GSK executives discussed, in email, whether to publish two GSK studies that also found problems with Avandia. In an email sent on July 20, 2001, a GSK executive responded, "Not a chance. These put Avnadia [sic] in quite a negative light when folks look at the response of the [Avandia] arm. It is a dificult [sic] story to tell and we would hope that these do not see the light of day. We have already published the better studies."

81. GSK created a sophisticated ghostwriting program called CASPPER. The Senate Finance Committee also discovered that Avandia was part of GSK's CASPPER program. For example, in an email sent on August 13, 2001, a GSK employee wrote, "[S]ee attached manuscript that has been ghostwritten for Haffner." Further down, the email continued, "Please find attached the Haffner manuscript... The manuscript is currently in a rough format that has not gone to the author yet." In an internal GSK memo written on September 13, 2000, GSK explained the value of CASPPER. According to the document:

> CASPPER provides you the ability to offer assistance in the preparation and publication of case studies and other short communications relevant to the clinical use of Avandia . . . Your participation can help establish or enhance your relationships with your physicians or other healthcare professionals.

82. In response to several document requests made to the FDA, the Senate Finance Committee also received and reviewed an analysis conducted by two FDA safety officials, Dr. David J. Graham, and Dr. Kate Gelperin. This analysis, conducted in October 2008, reviewed all available studies comparing Avandia (rosiglitazone) to Actos (pioglitazone). These FDA officials concluded:

> The risks of rosiglitazone use are serious and exceed those for pioglitazone. Rosiglitazone confers no unique and medically important benefit that distinguishes it from pioglitazone. The risks of rosiglitazone use exceed its benefits compared to pioglitazone. Rosiglitazone should be removed from the market.

83. In a study published in February 2010 in the journal for the American Diabetes Association, *Diabetes Care,* researchers at Harvard University sought to "identify potential association(s) of diabetic medications with myocardial infarction (MI)." As GSK purported to do in the ADOPT and RECORD studies, the researchers compared Avandia to the established

and much cheaper drugs metformin and sulfonylureas. They also included Actos. The study reviewed the charts for groups of 11,200, 12,490, 1,879, and 806 patients who were prescribed sulfonylurea, metformin, Avandia, or Actos, respectively. The Harvard study found that, compared to sulfonylurea, Avandia increased a diabetic's heart attack risk by an additional 30%. Significantly, when contrasted with GSK's claims to the contrary, the Harvard study showed that when compared to metformin, the "gold standard" in diabetes treatment, Avandia more than doubled a diabetic's risk of heart attack, increasing the risk by 120%. This led the authors dryly to conclude that "[o]ur results are consistent with a relative adverse cardiovascular risk profile for rosiglitazone." This is hardly the "significant advance" in diabetic care that GSK represented Avandia would be beginning in 1999 and continuing thereafter.

84. Despite the overwhelming evidence to the contrary, GSK has continued to deny that Avandia increases the risk of cardiac events, including at the FDA's Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, held on July 13-14, 2010. However, at that meeting, FDA reviewer Dr. Marciniak reported that RECORD "was inadequately designed and conducted to provide any reassurance about the CV safety risk of rosiglitazone." Dr. Marciniak also made the startling finding that the number of adverse cardiac events was not accurately reported in the RECORD study. Dr, Marciniak commented that "one does not have to be a mathematician or to perform calculations" to come to the conclusion that a combined look at all of the trials of Avandia would demonstrate that it causes heart attack. At the conclusion of that meeting, 22 out of 33 panel members voted to recommend to the FDA that Avandia should either be withdrawn from the market or have sales severely restricted.

85. On September 23, 2010, the FDA imposed strict restrictions on the further use of

Avandia. The FDA required that GSK develop a restricted access program for Avandia under a risk evaluation and mitigation strategy, or REMS. The REMS requires the following elements to assure safe use of Avandia:

(a) Provision of complete risk information to each patient and documentation in their medical record that the information has been received and understood;

(b) Documentation from health care providers that each patient receiving Avandia falls into one of two categories: (I) patients currently taking Avandia, or (ii) patients not already taking Avandia who are unable to achieve glycemic control on other medications and, in consultation with their health care professional, decide not to take Actos® for medical reasons;

(c) Documentation from health care providers that the risk information has been shared with each patient; and

(d) Physician, patient, and pharmacist enrollment in the REMS program.

In addition, the FDA halted the controversial Thiazolidinedione Intervention with Vitamin D Evaluation ("TIDE") clinical trial comparing Avandia to Actos®. *Id.* On that same date, European regulators stopped all sales of Avandia in Europe.

86. As shown herein, GSK's corporate strategy and business model is dictated not by science, but by sales and marketing. At GSK, marketing and commercial personnel exert extensive control over scientific and medical decisions, such as the initiation of clinical trials, the types of trials done, the design of those trials, and the reporting and publication of the data, all with the ultimate goal of producing further support for GSK's marketing messages and bolstering sales of Avandia. For example, on information and belief, GSK actively sought to create the impression that Avandia was better at lowering blood sugar than metformin, but intentionally avoided studying these two drugs head-to-head because it knew that if it did so, the studies would show GSK's claims to be false. GSK also obscured or failed to report important

safety information specifically relating to Avandia's cardiovascular risk, because doing so would jeopardize sales of Avandia and would be inconsistent with GSK's key marketing and sales messages—such as GSK's claim that Avandia, even though more expensive, ultimately was more cost effective than other type 2 diabetes therapies. Defendant failed to disclose Avandia's known side effects in the drug's package inserts and promotional materials. Instead, Defendant trained and encouraged its sales representatives to make false statements concerning the safety and efficacy of Avandia. GSK's top priority is neither science nor safety, but rather marketing. Marketing concerns infected and distorted GSK's entire Avandia scientific program.

87. Likewise, GSK maintained a marketing-based publication strategy to misleadingly influence the medical and scientific literature by promoting the publication of medical and scientific articles that would support its marketing message about Avandia's safety and efficacy and/or suggest dissatisfaction with competing therapies. On information and belief, this strategy included practices such as ghostwriting articles and hiring outside ghostwriting companies, giving GSK's marketing personnel editorial and substantive input into decisions about what scientific studies to publish and the actual content of such publications, and forming misleading financial and promotional relationships with authors, "opinion leaders" and other physicians. GSK gave its marketing department extensive control over the company's research and publication decisions so that medical and scientific publications could be used as tools to promote its marketing messages about Avandia. Defendant's contrived, self-funded studies were materially misleading in that they failed to employ proper scientific methodology, clinical research techniques, and data interpretation, neglected to accurately report results in conducting these studies to support their promotional campaign, and distorted the data derived from their flawed studies in their publication of that data.

88. GSK's far-reaching, massive, and widespread promotional campaign to drive Avandia's sales was specifically directed at and did influence the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants. GSK sales representatives, lobbyists, GSK "opinion leaders", and company "scientists" directly communicated with the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants, and in connection therewith, presented false and misleading information regarding the safety and efficacy of Avandia which was reasonably relied upon by the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants.

89. In addition, GSK, through its control and manipulation of studies and research publications, its sponsorship of medical education programs, its submission of false and misleading information to the FDA, its use of GSK "opinion leaders", its failure to adequately warn of Avandia's true risks in its labeling and other marketing materials, and its false and deceptive marketing conducted by GSK sales representatives, lobbyists, GSK "opinion leaders", and company "scientists", caused false and misleading information regarding the safety and efficacy of Avandia to be reasonably relied upon by the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants.

90. In 2007, the State of Utah passed legislation allowing the Division of Health Care Financing to establish a Preferred Drug List to operate with the pharmacy program and at the Division's discretion. The Division then promulgated rule R414-60B of the Utah Administrative Code, which defined the responsibilities and functions of the P&T Committee, which include reviewing drug classes and making recommendations to the Division for PDL implementation.

91. On or about October 19, 2007, the P&T Committee met to consider whether to include Avandia and Actos on the PDL. In connection with that meeting, GSK unleashed its full marketing force on the Utah Medicaid program in an effort to assure that Avandia was included on the Utah PDL. GSK was well aware that one of the primary issues that the Committee would be considering was whether there were substantial differences in safety or efficacy between Avandia and Actos. Upon information and belief, before the meeting, GSK sales representatives, lobbyists or other agents or representatives contacted the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants, and provided information regarding Avandia in an effort to influence the P&T Committee's decision regarding Avandia. Deborah Griffis, the GSK Regional Medical Scientist, appeared before the P&T Committee, and in her testimony misrepresented the safety and efficacy profile of Avandia. In addition, upon information and belief, GSK arranged for "opinion leaders" to testify at the hearing on behalf of Avandia, without disclosing to the Committee that their testimony had been arranged by GSK. In addition, upon information and belief, GSK arranged to have physicians submit letters of support for Avandia without disclosing GSK's role in obtaining these letters of support. GSK's efforts to influence the Committee were successful, and Avandia was placed on the Utah PDL, even though GSK knew full well, from its own hidden testing, that the safety and efficacy of Avandia was not equal to Actos.

92. GSK engaged in a premeditated program to influence prescribers, Medicaid recipients, and the State of Utah to believe that Avandia was a superior drug when it was not, and to believe that Avandia was cardio-protective when it was not.

93. Moreover, from the time it first went on the market, Avandia's price was grossly inflated compared to older diabetic drugs.

94. The financial toll that GSK's false and deceptive marketing of Avandia has had on the State of Utah has been dramatic. Relying upon GSK's promises of superior treatment and better cardiovascular outcomes compared with the older diabetes drugs, such as metformin and sulfonylureas, the State of Utah paid a hefty premium for a drug that in truth was no more efficacious than far cheaper drugs, but was far more dangerous to Utah Medicaid recipients.

95. As the diabetes problem has grown in Utah, the State of Utah has had to shoulder an increasing share of the burden of treating diabetics, particularly in indigent and low-income populations, and the weight of that responsibility continues to grow. The State of Utah seeks the most effective and safest treatment for its residents and relies on pharmaceutical companies to fairly and accurately represent the safety and efficacy of their products. GSK has wholly violated that trust, and instead has perpetrated its fraudulent scheme to defraud the State of Utah, and has bilked the State of Utah out of millions of dollars by making false representations that Avandia was better at lowering blood sugar than existing medications, and could decrease diabetics' cardiovascular risks.

96. To treat patients with Type 2 diabetes, the State of Utah purchased millions of dollars' worth of Avandia starting in 1999, relying on GSK's false and misleading representations that Avandia was a safe and effective treatment for Type 2 diabetes. GSK's deception increased the costs to the State of Utah through the higher price of Avandia when cheaper and safer alternatives were available. Further the State of Utah bears the additional treatment and hospitalization costs of the heart attacks and other cardiovascular problems caused by Avandia to its Medicaid recipients, including, but not limited to, heart attacks, strokes, and sudden cardiac death. GSK could have prevented these increased costs had it been forthcoming with the State of Utah, the medical and scientific community, and consumers about the risks of Avandia.

97. GSK's false, misleading, and deceptive marketing of Avandia resulted in millions of dollars of Avandia sales to the State of Utah, sales that otherwise would not have been made. GSK was unjustly enriched and profited from the suppression of the truth and misleading promotion of Avandia

98. GSK's false, misleading and deceptive marketing of Avandia also resulted in those Utah Medicaid recipients who took Avandia experiencing cardiovascular side effects including, but not limited to, heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, stroke and/or severe injury to the heart leading to cardiac arrest, and death, requiring otherwise avoidable hospitalizations and medical care and treatment. As a result, the State of Utah bore additional costs for the care and treatment of these undisclosed increased cardiovascular risks.

99. As result of GSK's improper, false, and misleading marketing of Avandia, the State of Utah, through its Medicaid program, has been injured as a result of the Defendant's actions, actions which caused the submission of False Claims to the Utah Medicaid program. Those injuries include the costs of prescriptions that should not have been paid, as well as consequential damages to the Utah Medicaid population that have been and will be incurred as a result of the ingestion of Avandia. Defendant knew, deliberately ignored, or acted in reckless disregard in subjecting the Utah Medicaid population to disability or death through the ingestion of Avandia, and in causing the submission of False Claims to the Utah Medicaid program.

100. This Complaint is based solely upon the laws of the State of Utah, and contains causes of action found within those laws. To the extent that the Defendant asserts that any claim contained herein raises a substantial question of federal law or a federal cause of action, Plaintiff hereby disavows any such claim.

FIRST CLAIM FOR RELIEF
(Equitable Tolling of Applicable Statutes of Limitations)

101. Plaintiff repeats and reiterates the allegations previously set forth herein.

102. The running of any statute of limitations has been tolled by reason of GSK's fraudulent concealment. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff the true risks associated with taking Avandia.

103. As a result of GSK's actions, Plaintiff and, upon information and belief, Utah Medicaid recipients and prescribers within the State of Utah, were unaware, and could not reasonably have known or have learned through reasonable diligence, the true risks associated with taking Avandia and that the concealment of those risks were the direct and proximate result of Defendant's acts and omissions.

104. Furthermore, GSK is estopped from relying on any statute of limitations because of its fraudulent concealment of the true character, quality and nature of Avandia. Defendant was under a duty to disclose the true character, quality and nature of Avandia because this was non-public information over which the Defendant had and continues to have exclusive control, and because the Defendant knew that this information was not available to the Plaintiff, Utah Medicaid recipients, and prescribers within the State of Utah. In addition, the Defendant is estopped from relying on any statute of limitations because of its intentional concealment of these facts.

105. Plaintiff had no knowledge that the Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendant, the Plaintiff could not have reasonably discovered the wrongdoing. Also, the economics of this fraud should be considered. The Defendant had the ability to and did spend enormous amounts of money in furtherance of its purpose of marketing and promoting a profitable drug,

notwithstanding the known or reasonably known risks. Plaintiff, Utah Medicaid recipients, and prescribers within the State of Utah could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on the Defendant's representations.

SECOND CLAIM FOR RELIEF
(Utah False Claims Act, UCA § 26-20-7)

Mispresentation of Type and Quality of Items Rendered

106. Plaintiff repeats and reiterates the allegations previously set forth herein.

107. Pursuant to the Utah False Claims Act, it is illegal to make a claim for medical benefits which misrepresents the type, quality or quantity of items or services rendered. Similarly, causing such a claim to be made, or aiding and abetting such a claim, is also prohibited.

108. In representing that Avandia had superior efficacy than other established drugs, that patients could stay on Avandia longer than the older drugs, and that Avandia had the additional benefit of actually lowering diabetics' cardiovascular risks, GSK misrepresented the type and/or quality of Avandia and either caused claims to be made by prescribers and Medicaid recipients under the Utah False Claims Act, or aided and abetted such claims to be made. Such claims would not have been made and/or paid had GSK truthfully and accurately disclosed the true efficacy of Avandia and the true cardiovascular risks of Avandia, risks that were known by GSK but not disclosed to the State of Utah, Utah Medicaid recipients, and/or prescribers within the State of Utah. On information and belief, GSK's clinical research and publication strategies were directed and influenced largely by marketing concerns rather than by medical or safety concerns, and GSK's management allowed marketing personnel to direct the company's so-called scientific research rather than enabling independent analysis. GSK repeatedly failed to disclose important safety information; it improperly and deceptively influenced the medical and

scientific literature and the perception of Avandia within the medical community; it consistently downplayed Avandia's risks; it formed deceptive and misleading financial and promotional relationships with "opinion leaders," speakers and other physicians for the purpose of promoting the product; it engaged in misleading sales training, sales tactics, and marketing to prescribers, Medicaid recipients, and/or the State of Utah that misrepresented the safety and efficacy of Avandia; it engaged in the ghostwriting of medical and scientific articles; and it engaged in other deceptive and misleading marketing, lobbying, public relations, and sales practices as described herein.

109. GSK's far-reaching, massive, and widespread promotional campaign to drive Avandia's sales was specifically directed at and did influence the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants. GSK sales representatives, lobbyists, GSK "opinion leaders", and company "scientists" directly communicated with the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants, and in connection therewith, presented false and misleading information regarding the safety and efficacy of Avandia which was reasonably relied upon by the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants.

110. In addition, GSK, through its control and manipulation of studies and research publications, its sponsorship of medical education programs, its submission of false and misleading information to the FDA, its use of GSK "opinion leaders", its failure to adequately warn of Avandia's true risks in its labeling and other marketing materials, and its false and deceptive marketing conducted by GSK sales representatives, lobbyists, GSK "opinion leaders," and company "scientists,", caused false and misleading information regarding the safety and

efficacy of Avandia to be reasonably relied upon by the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants.

111. GSK's aggressive, illegal promotions have induced a misallocation of State Medicaid funds through a pattern of fraudulent conduct which caused false claims to be submitted to the Utah Medicaid program. Defendant executed and conspired to execute a plan to defraud the Utah Medicaid program in connection with the delivery of or payment for Avandia. Defendant's plan included the implementation of intentionally deceptive marketing schemes. Defendant intended that its fraudulent promotion result in the reimbursement of prescriptions by the Utah Medicaid program.

112. As a result of GSK's fraudulent marketing of Avandia, the State of Utah has paid millions of dollars for Avandia and has paid excessive prices for Avandia. As a result, GSK has been illegally enriched at the expense of the State. Further, the State has been required and will be required to pay the costs of treatment for state residents actively harmed by GSK's actions.

113. In making representations that Avandia had superior efficacy over other established drugs, that patients could stay on Avandia longer than the older drugs, and that Avandia had the additional benefit of actually lowering diabetics' cardiovascular risks, GSK acted with actual knowledge of the falsity of the representations or acted in either deliberate ignorance or reckless disregard of the truth or falsity of the information.

114. Accordingly, under the Utah False Claims Act, the State is entitled to restitution for all damages sustained by the State because of GSK's violations of the Utah False Claims Act, and a civil penalty equal to three times the damages sustained by the State because of GSK's violations of the Utah False Claims Act and not less than $5,000 or more than $10,000 for each claim filed or act done in violation of the Utah False Claims Act.

115. In addition, the State seeks the costs of enforcement, including the cost of investigators, attorneys, and other state employees.

THIRD CLAIM FOR RELIEF
(Utah False Claims Act, UCA § 26-20-7)

Items Which Were Not Medically Necessary

116. Plaintiff repeats and reiterates the allegations previously set forth herein.

117. Pursuant to the Utah False Claims Act, it is illegal to make a claim for medical benefits for which the person knows was not medically necessary. Similarly, causing such a claim to be made, or aiding and abetting such a claim, is also prohibited.

118. In representing that Avandia had superior efficacy than other established drugs, that patients could stay on Avandia longer than the older drugs, and that Avandia had the additional benefit of actually lowering diabetics' cardiovascular risks, GSK actively promoted the use Avandia for non-medically necessary uses, and either caused claims to be made by prescribers and Medicaid recipients under the Utah False Claims Act, or aided and abetted such claims to be made. Such claims would not have been made and/or paid had GSK truthfully and accurately disclosed the true efficacy of Avandia and the true cardiovascular risks of Avandia, risks that were known by GSK but not disclosed to the State of Utah, Utah Medicaid recipients, and/or prescribers within the State of Utah. On information and belief, GSK's clinical research and publication strategies were directed and influenced largely by marketing concerns rather than by medical or safety concerns, and GSK's management allows marketing personnel to direct the company's so-called scientific research rather than enabling independent analysis. GSK repeatedly failed to disclose important safety information; it improperly and deceptively influenced the medical and scientific literature and the perception of Avandia within the medical community; it consistently downplayed Avandia's risks; it formed deceptive and misleading

financial and promotional relationships with "opinion leaders," speakers and other physicians for the purpose of promoting the product; it engaged in misleading sales training, sales tactics, and marketing to prescribers, Medicaid recipients, and/or the State of Utah that misrepresented the safety and efficacy of Avandia; it engaged in the ghostwriting of medical and scientific articles; and it engaged in other deceptive and misleading marketing, lobbying, public relations, and sales practices as described herein.

119. GSK's far-reaching, massive, and widespread promotional campaign to drive Avandia's sales was specifically directed at and did influence the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants. GSK sales representatives, lobbyists, GSK "opinion leaders", and company "scientists" directly communicated with the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants, and in connection therewith, presented false and misleading information regarding the safety and efficacy of Avandia which was reasonably relied upon by the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants.

120. In addition, GSK, through its control and manipulation of studies and research publications, its sponsorship of medical education programs, its submission of false and misleading information to the FDA, its use of GSK "opinion leaders", its failure to adequately warn of Avandia's true risks in its labeling and other marketing materials, and its false and deceptive marketing conducted by GSK sales representatives, lobbyists, GSK "opinion leaders," and company "scientists,", caused false and misleading information regarding the safety and efficacy of Avandia to be reasonably relied upon by the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants.

121. GSK's aggressive, illegal promotions have induced a misallocation of State Medicaid funds through a pattern of fraudulent conduct which caused false claims to be submitted to the Utah Medicaid program.

122. As a result of GSK's fraudulent marketing of Avandia, the State of Utah has paid millions of dollars for Avandia and has paid excessive prices for Avandia. As a result, GSK has been illegally enriched at the expense of the State. Further, the State has been required and will be required to pay the costs of treatment for state residents actively harmed by GSK's actions.

123. Defendant knowingly caused false claims for payment to be submitted to the State's Medicaid program by intentionally promoting non-medically necessary uses of Avandia to prescribers for the purpose of receiving greater compensation than that to which it is legally entitled, with the costs ultimately being borne by the State through its Medicaid reimbursement. These submissions are false because they are not medically necessary.

124. Defendant executed and conspired to execute a plan to defraud the Utah Medicaid program in connection with the delivery of or payment for Avandia for non-medically necessary uses. Defendant's plan included the implementation of intentionally deceptive marketing schemes. Defendant intended that its fraudulent promotion result in the reimbursement of prescriptions by Medicaid.

125. In making representations that Avandia had superior efficacy over other established drugs, that patients could stay on Avandia longer than the older drugs, and that Avandia had the additional benefit of actually lowering diabetics' cardiovascular risks, GSK acted with actual knowledge of the falsity of the representations or acted in either deliberate ignorance or reckless disregard of the truth or falsity of the information.

126. Accordingly, under the Utah False Claims Act, the State is entitled to restitution for all

damages sustained by the State because of GSK's violations of the Utah False Claims Act, and a civil penalty equal to three times the damages sustained by the State because of GSK's violations of the Utah False Claims Act and not less than $5,000 or more than $10,000 for each claim filed or act done in violation of the Utah False Claims Act.

127. In addition, the State seeks the costs of enforcement, including the cost of investigators, attorneys, and other state employees.

FOURTH CLAIM FOR RELIEF
(Strict Products Liability - Failure to Warn)

128. Plaintiff repeats and reiterates the allegations previously set forth herein.

129. Defendant GSK is the manufacturer and/or supplier of Avandia.

130. The Avandia manufactured and/or supplied by Defendant GSK was and is unaccompanied by proper warnings or packaging regarding all possible side effects associated with the drug. GSK failed to warn of the comparative severity, incidence, and duration of such adverse effects. The warnings given to the State, prescribers, and Medicaid recipients did not accurately reflect the signs, symptoms, incidents, or severity of the side effects of Avandia.

131. GSK failed to adequately test Avandia. Such testing would have shown that Avandia possessed serious potential side effects, of which full and proper warnings should have been made.

132. The Avandia manufactured or supplied by GSK was defective due to inadequate post-marketing warnings, packaging, or instructions. After GSK knew or should have known of the risks of injury from Avandia, it failed to provide adequate warnings to prescribers, Medicaid recipients, or the State as the prescribers, users, and financially responsible party, respectively. Further, GSK continued to aggressively market Avandia in spite of these defects and risks.

133. Based on information and belief, GSK actually knew of the defective nature of Avandia,

but continued to market and sell Avandia without proper warning, so as to maximize sales and profits in conscious disregard for the foreseeable harm caused by Avandia.

134. As a proximate cause and legal result of GSK's failure to warn of known and reasonably knowable dangers associated with the use of Avandia, the State of Utah has suffered and will continue to suffer damages and is entitled to recover those damages.

FIFTH CLAIM FOR RELIEF
(Strict Products Liability - Design Defect)

135. Plaintiff repeats and reiterates the allegations previously set forth herein.

136. At all times material and relevant to this action, Avandia was defective in design and manufacture, and was so at the time it was prescribed by prescribers participating in the Utah Medicaid program. Avandia was defective and dangerous in that it caused serious injuries and illness when used for its intended and foreseeable purpose.

137. The defects in Avandia were known to GSK at the time of approval by the FDA. The required disclosures from GSK were inaccurate, incomplete, misleading, and fraudulent. These misrepresentations were material to the State.

138. GSK knew Avandia would be used by consumers without inspection for defect and that the State, prescribers, and users of Avandia were relying upon GSK's representations that the product was safe.

139. Adequate pre-approval testing would have revealed the full extent of the dangers of Avandia, and would have shown that Avandia could cause extensive medical complications and injuries.

140. As a proximate and legal result of the design defect, as well as GSK's failure to adequately test the product so as to discover the defect, the State of Utah has suffered and will continue to suffer damages and is entitled to recover those damages.

SIXTH CLAIM FOR RELIEF
(Fraud and Negligent Misrepresentation)

141. Plaintiff repeats and reiterates the allegations previously set forth herein.

142. GSK's warnings of Avandia's side effects contained false representations and/or failed to accurately represent the material facts of the full range and severity of risks and adverse reactions associated with the product.

143. GSK's Avandia-related claims and assertions to the State of Utah, prescribers, and Medicaid recipients contained false representations as to the safety of Avandia and its defective design.

144. GSK was negligent in not making accurate representations regarding the side effects and adverse medical conditions associated with the use of Avandia.

145. GSK knew or reasonably should have known through adequate testing that the claims made to the State with regard to the safety and efficacy of Avandia were false or incomplete, and misrepresented the material facts of Avandia's unsafe and defective condition.

146. The State, through its Medicaid program, expended millions of dollars for Avandia prescriptions which were directly caused by the fraudulent and misleading statements of the Defendant.

147. Defendant willfully, knowingly and deceptively withheld material facts regarding the risks and side effects associated with Avandia from Utah physicians treating Medicaid recipients.

148. Defendant intentionally withheld information regarding the safety risks and side effects associated with Avandia with the intent to induce the State of Utah, prescribers and Medicaid recipients.

149. The State of Utah, prescribers and Medicaid recipients were justified in their reliance on Defendant to educate them as to the risks and dangerous and potentially life-threatening side

effects associated with Avandia use.

150. GSK's far-reaching, massive, and widespread promotional campaign to drive Avandia's sales was specifically directed at and did influence the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants. GSK sales representatives, lobbyists, GSK "opinion leaders", and company "scientists" directly communicated with the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants, and in connection therewith, presented false and misleading information regarding the safety and efficacy of Avandia which was reasonably relied upon by the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants.

151. In addition, GSK, through its control and manipulation of studies and research publications, its sponsorship of medical education programs, its submission of false and misleading information to the FDA, its use of GSK "opinion leaders", its failure to adequately warn of Avandia's true risks in its labeling and other marketing materials, and its false and deceptive marketing conducted by GSK sales representatives, lobbyists, GSK "opinion leaders," and company "scientists,", caused false and misleading information regarding the safety and efficacy of Avandia to be reasonably relied upon by the State of Utah, its Drug Utilization Review Board, its P&T Committee Members, and/or its advisory consultants.

152. GSK's aggressive, illegal promotions have induced a misallocation of State Medicaid funds through a pattern of fraudulent conduct which caused false claims to be submitted to the Utah Medicaid program. Defendant executed and conspired to execute a plan to defraud the Utah Medicaid program in connection with the delivery of or payment for Avandia. Defendant's plan included the implementation of intentionally deceptive marketing schemes. Defendant

intended that its fraudulent promotion result in the reimbursement of prescriptions by the Utah Medicaid program.

153. Each of the Defendant's misleading and deceptive statements, representations and advertisements related to Avandia were material to the State's reimbursement of Avandia.

154. As a proximate and legal result of GSK's fraudulent misrepresentations, the State of Utah has suffered and will continue to suffer damages, and is therefore entitled to recover for those damages.

SEVENTH CLAIM FOR RELIEF
(Negligence)

155. Plaintiff repeats and reiterates the allegations previously set forth herein.

156. GSK owed a duty to exercise reasonable care in the testing, marketing, manufacture, sales, labeling, and/or distribution of Avandia, including a duty to ensure that users would not suffer from unreasonable, dangerous, undisclosed, or misrepresented side effects. GSK owed this duty to the State of Utah, as the State funded the distribution of Avandia to Utah Medicaid recipients.

157. GSK breached this duty, as it was negligent in the testing, marketing, manufacture, sale, labeling and distribution of Avandia. As a direct and proximate result of Defendant GSK's negligence, the State of Utah has suffered and will suffer the damages and is therefore entitled to recover those damages.

EIGHTH CLAIM FOR RELIEF
(Breach of Express Warranty)

158. Plaintiff repeats and reiterates the allegations previously set forth herein.

159. In marketing Avandia and promoting its use in the Utah Medicaid program, Defendant GSK expressly warranted to the State, prescribers, and Medicaid recipients that Avandia was

safe, effective, and fit for its intended use. Pursuant to UCA § 70A-2-313, these express warranties were created by and through statements made by Defendant's authorized agents or sales representatives, orally and in publications, package inserts, and in other written materials intended for the State, prescribers and Medicaid recipients.

160. The State, prescribers, and Medicaid recipients relied on these express warranties.

161. GSK breached these express warranties due to Avandia's defective nature and the fact that the drug was not safe, effective, or fit for its intended use. Rather, Avandia carries unreasonable and undisclosed risks in breach of the express warranties.

162. As a direct and legal result of this breach of warranty, the State of Utah has suffered and will continue to suffer damages and is entitled to recover for those damages.

NINTH CLAIM FOR RELIEF
(Breach of Implied Warranty)

163. Plaintiff repeats and reiterates the allegations previously set forth herein.

164. Pursuant to UCA § 70A-2-314, through the manufacture, marketing, and sale of Avandia, Defendant GSK impliedly warranted to the State of Utah, prescribers, and Medicaid recipients that Avandia was of merchantable quality - safe and fit for its intended use.

165. At all times relevant to this action, Defendant GSK also had reason to know of the particular purpose for which the State, prescribers, and Medicaid recipients were purchasing and using Avandia, i.e., for the treatment of diabetes. Therefore, pursuant to UCA § 70A-2-315, Defendant GSK impliedly warranted to the State of Utah, prescribers, and Medicaid recipients that Avandia was fit for that particular purpose.

166. Defendant GSK had reason to know through actual or constructive knowledge that the State of Utah, prescribers, and Medicaid recipients were reasonably relying upon the skill, judgment, and implied warranties of Defendant in approving, prescribing, and using Avandia.

167. Defendant GSK breached the implied warranties of merchantability and of fitness for a particular purpose in that Avandia is not of merchantable quality, not safe for its intended use, and not safe for its particular purpose. This is because Avandia had dangerous and undisclosed propensities when ingested, resulting in severe illness and injury to many of its users.

168. As a direct and legal result of this breach of warranty, the State of Utah has suffered and will continue to suffer damages and therefore is entitled to recover those damages.

TENTH CLAIM FOR RELIEF
(Pattern of Unlawful Activity, UCA § 76-10-1601 et seq.)

169. Plaintiff repeats and reiterates the allegations previously set forth herein.

170. GSK constitutes an "enterprise" within the meaning of UCA § 76-10-1602(1).

171. GSK has engaged in a pattern of illegal activity in its advertising, sales, marketing, and distribution as described above. These actions meet the definition of "Pattern of Unlawful Activity" set out in UCA §§ 76-10-1602(2) and 76-10-1602(4)(d).

172. GSK has committed unlawful acts under UCA § 76-10-1603 in that it has received proceeds derived from a pattern of unlawful activity.

173. The State, as an injured party, may sue in District Court and recover twice the damages sustained as a result of GSK's unlawful acts.

174. The State, as an injured party, is entitled to an award of reasonable attorney's fees incurred in enforcing its rights.

ELEVENTH CLAIM FOR RELIEF
(Unjust Enrichment)

175. Plaintiff repeats and reiterates the allegations previously set forth herein.

176. Defendant knowingly, willfully and intentionally marketed and promoted Avandia in a false and deceptive manner.

177. Defendant knowingly, willfully and intentionally withheld information from the State, prescribers and Medicaid recipients regarding the risks associated with Avandia use.

178. The State paid, reimbursed or otherwise conferred a benefit upon Defendant that directly resulted from the Defendant's fraudulent marketing practices.

179. Further, Defendant has been unjustly enriched as a result of its fraudulent marketing practices.

180. Plaintiff is entitled to restitution to the extent of the increased revenue received by the Defendant from Avandia prescriptions that were reimbursed by the State and which resulted from Defendant's deceptive and illegal marketing program.

TWELFTH CLAIM FOR RELIEF
(Truth in Advertising, UCA § 13-11a-1 et seq.)

181. Plaintiff repeats and reiterates the allegations previously set forth herein.

182. GSK constitutes a "person" within the meaning of UCA § 13-11a-2(7).

183. GSK has engaged in deceptive trade practices as described above by representing that Avandia had characteristics, benefits, and/or qualities that it does not have and/or by representing that Avandia was of a particular standard, quality, or grade when, in fact, the drug was not of that standard, quality, or grade. These actions meet the definition of "deceptive trade practices" set out in UCA § 13-11a-3.

184. The State, as an injured party, may sue in District Court and recover damages sustained as a result of GSK's unlawful acts.

185. The State, as an injured party, is entitled to an award of costs and reasonable attorney's fees incurred in enforcing its rights.

JURY DEMAND

The State respectfully requests a trial by jury pursuant to Rule 38, Utah R. Civ. Pro.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the State of Utah, prays for judgment against GSK as follows:

1. For all damages sustained by the State;

2. For the Avandia-related damages of past, present, and future medical expenses for recipients of the Utah Medicaid program;

3. The cost of all Avandia prescriptions paid by the State;

4. Restitution for all damages sustained by the State because of GSK's violations of the Utah False Claims Act;

5. For triple damages as a civil penalty pursuant to the Utah False Claims Act;

6. For an additional civil penalty of not less than $5,000 or more than $10,000 for each claim filed or act done in violation of the Utah False Claims Act;

7. For the cost of enforcement, including the cost of attorneys, investigators, and other state employees, pursuant to the Utah False Claims Act;

8. For twice the damages suffered pursuant to the violations of the Utah Pattern of Unlawful Activity Act pled;

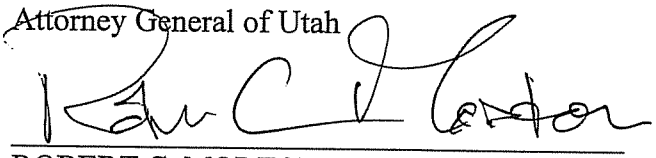
9. For actual damages suffered pursuant to the violations of the Utah Truth in Advertising Act;

10. For punitive damages; and,

11. For such other and further relief as may be justified and which Plaintiff may be entitled to by law including, but not limited to, all court costs, witness fees, and deposition fees.

Respectfully submitted,

MARK L. SHURTLEFF
Attorney General of Utah



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